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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,350	02/18/2004	Wisam Breegi	EYE-011	9204

40336 7590 01/30/2007

(OSI) EYETECH, INC.
41 PINELAWN ROAD
MELVILLE, NY 11747

EXAMINER	
CRAIG, PAULA L	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,350	BREEGI ET AL.	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *3,11-15,19-23 and 27-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,16-18 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/15/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and Species A in the reply filed on May 15, 2006 is acknowledged. Species A includes Claims 1-2, 4-10, 16-18, and 24-26. Claims 3, 11-15, 19-23, and 27-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: DRUG DELIVERY DEVICE HAVING A PRESSURE EQUALIZATION ELEMENT.

3. The use of the trademarks "Dacron" and "Mylar" has been noted in this application. These marks should be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 9 is objected to because of the following informalities: Claim 9 contains the trademark/trade names Dacron and Mylar. A trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,604,417 to Stolzenberg et al.

7. For Claim 1, Stolzenberg teaches a device for delivery of a therapeutic agent to a treatment site (Figs. 1-2, Abstract, and col. 1, lines 60-68). The device has an outer layer adapted for placement of the device at an internal body site (outer layer is osmotic pressure solvent chamber 1 and medicament dispensing vessel 8; Figs. 1-2 and col. 2, lines 6-25). Stolzenberg teaches a reservoir within the outer layer, the reservoir adapted to form a closed system when containing a therapeutic agent (reservoir is medicament chamber 11, Fig. 2 and col. 2, lines 25-29). Stolzenberg teaches a

pressure equalization element adapted to maintain a substantially constant pressure within the closed system (pressure equalization element is dispensing orifice 9, pistons 4 and 10, and membrane 14, Figs. 1-2, col. 1, lines 26-69, and col. 2, lines 6-73).

8. For Claim 2, Stolzenberg teaches the pressure equalization element including a membrane disposed within the outer layer, the membrane dividing the interior of the outer layer into a pressure equalizing chamber and a therapeutic agent chamber, wherein the volume of the pressure equalizing chamber changes in response to the volume in the therapeutic agent chamber in order to maintain a substantially constant pressure within the volume of the outer layer (membrane is membrane 14, pressure equalizing chamber is chamber 2, therapeutic agent chamber is chambers 11 and 12, Fig. 2, col. 2, lines 53-73; note that as the volume in chamber 11 decreases, the volume of the pressure equalizing chamber changes in response).

9. For Claim 18, Stolzenberg teaches a therapeutic agent disposed in the reservoir (col. 1, lines 7-60, col. 2, lines 20-29).

10. Claims 1, 2, 4, 8-10, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,760,984 to Theeuwes.

11. For Claim 1, Theeuwes teaches a device for delivery of a therapeutic agent to a treatment site (device 10, Figs. 1-3, col. 1, lines 5-16, col. 2, lines 16-21, and col. 8, lines 37-68). The device has an outer layer adapted for placement of the device at an internal body site (outer layer is outer wall 20, Fig. 2 and col. 3, lines 36-47). Theeuwes teaches a reservoir within the outer layer, the reservoir adapted to form a closed system

when containing a therapeutic agent (reservoir is compartment 16, Fig. 2 and col. 3, lines 26-31). Theeuwes teaches a pressure equalization element adapted to maintain a substantially constant pressure within the closed system (pressure equalization element is inner wall 15, layer 21, and dispensing passageway 17, Figs. 1-3 and col. 3, lines 20-62).

12. For Claim 2, Theeuwes teaches the pressure equalization element including a membrane disposed within the outer layer, wherein the membrane divides the interior of the outer layer into a pressure equalizing chamber and a therapeutic agent chamber, wherein the volume of the pressure equalizing chamber changes in response to the volume in the therapeutic agent chamber in order to maintain a substantially constant pressure within the volume of the outer layer (membrane is inner wall 15; pressure equalizing chamber is located between inner wall 15 and outer wall 20; Figs. 1-3, col. 3, line 11 to col. 4, line 65, col. 5, lines 40-68; note that the overall pressure within the outer layer, including both the pressure equalizing chamber and the therapeutic agent chamber, remains constant as the volume in the therapeutic agent chamber decreases).

13. For Claim 4, Theeuwes teaches a rate controlling membrane disposed between the membrane and the internal body surface (the rate controlling membrane is outer wall 20, Figs. 1-3 and col. 4, line 53, to col. 5, line 39).

14. For Claim 8, Theeuwes teaches the membrane being flexible (inner wall 15 is flexible, col. 3, lines 20-24, and Claim 1).

15. For Claim 9, Theeuwes teaches the membrane being polyethylene (col. 7, lines 24-37).

16. For Claim 10, Theeuwes teaches a port through which a therapeutic agent can be injected into the therapeutic agent chamber (filling port 18, Figs. 1-3 and col. 3, lines 29-37).

17. For Claim 16, Theeuwes teaches the outer layer being a biocompatible, non-bioerodable material (col. 4, line 53 to col. 5, line 39).

18. For Claim 17, Theeuwes teaches the biocompatible, non-bioerodable material being polystyrene or urethane (col. 5, lines 23-34).

19. For Claim 18, Theeuwes teaches a therapeutic agent disposed in the reservoir (col. 8, line 19 to col. 9, line 37).

20. Claims 1, 5-7, 16-18, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,725,493 to Avery et al.

21. For Claim 1, Avery teaches a device for delivery of a therapeutic agent to a treatment site (Figs. 1-19, col. 2, lines 31-36). The device has an outer layer adapted for placement of the device at an internal body site (outer layer is housing 80 or 80' and tube 140, Figs. 1-19 and col. 4, lines 38-61). Avery teaches a reservoir within the outer layer, the reservoir being adapted to form a closed system when containing a therapeutic agent (reservoir is reservoir 110 or 110', Figs. 1-19, col. 5, lines 13-65, col. 6, lines 19-33, col. 7, lines 23-32, col. 10, lines 54-65; note that the tube 140 may be a small diameter or capillary tube, which limits discharge of medication and maintains pressure in the system; the tip 166 or 166' of the tube 140 may also include a filter 352 or membrane 360). Avery teaches a pressure equalization element adapted to maintain

a substantially constant pressure within the closed system (pressure equalization element is tube 140 or 140'; Figs. 1-19, col. 7, lines 49-56, and col. 8, lines 9-15; note that when medication is injected into reservoir 110, the increased pressure is relieved by passage of fluid through tube 140).

22. For Claim 5, Avery teaches the outer layer including an attachment element adapted for fixing the outer layer to an internal body surface (attachment element is tube 140 or 140', bottom wall 84 or 84' and suturing or fixation tabs 98, 102, and 172, Figs. 1-19, col. 4, lines 52-65, col. 6, line 56 to col. 7, line 22, col. 8, lines 49-57).

23. For Claim 6, Avery teaches the attachment element including a rim (rim is the edge of tube 140 or 140', bottom wall 84 or 84' and tabs 98, 102, and 172, Figs. 1-19, col. 4, lines 52-65, col. 6, line 56 to col. 7, line 22, col. 8, lines 49-57).

24. For Claim 7, Avery teaches a base that is contiguous with the rim and contacts the internal body site and that has one or more openings to allow a therapeutic agent contained within the reservoir to contact the body site (base is the elbow 160, 160a or 160b and intravitreal extension 164; the opening is at tip 166 or 166', Figs. 1-19, col. 7, lines 1-22).

25. For Claim 16, Avery teaches the outer layer being a biocompatible, non-bioerodable material (tantalum, col. 4, line 62 to col. 5, line 2).

26. For Claim 17, Avery teaches the biocompatible, non-bioerodable material being tantalum (col. 4, line 62 to col. 5, line 2).

27. For Claim 18, Avery teaches a therapeutic agent disposed in the reservoir (col. 7, lines 23-32).

28. For Claim 24, Avery teaches a catheter having a first end in fluid communication with the reservoir and a second end adapted for placement at an administration site (catheter is tube 140 or 140', Figs. 1-19, col. 6, line 56 to col. 7, line 22).

29. For Claims 25-26, Avery teaches the device being affixed to the sclera throughout the circumference of the rim (Figs. 1-2 and 8-9, col. 4, lines 38-51, col. 6, line 56 to col. 7, line 22).

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Nos. 4,135,514 to Zaffaroni et al. and 6,375,972 to Guo et al. teach drug delivery devices having a pressure equalization element configured for use in the eye. U.S. Patent Nos. 3,786,813 to Michaels and 3,901,232 to Michaels et al. teach drug delivery devices including a gas-filled pressure equalizing chamber. The remaining prior art references listed on the accompanying Form PTO-892 show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on 8:30AM-4:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
PRIMARY EXAMINER